



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,125	03/28/2001	Etsuya Matsutani	2556USOP	7053

23115 7590 05/23/2003

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC
INTELLECTUAL PROPERTY DEPARTMENT
475 HALF DAY ROAD
SUITE 500
LINCOLNSHIRE, IL 60069

EXAMINER

RAWLINGS, STEPHEN L

ART UNIT	PAPER NUMBER
----------	--------------

1642

DATE MAILED: 05/23/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, DC 20231
www.uspto.gov

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
---------------------------------	-------------	---	---------------------

EXAMINER

ART UNIT	PAPER
----------	-------

14

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents

The communication filed on 01 May 2003 is not fully responsive to the Office communications mailed 07 April 2003, 07 February 2003, 11 December 2002, and 27 August 2002 for the reason(s) set forth on the attached Notice to Comply With the Sequence Rules or CRF Diskette Problem Report. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

If a complete reply has not been submitted by the time the period set in the Office communication mailed 07 April 2003 has expired, this application will become abandoned under 37 CFR 1.821(g) unless applicant corrects the deficiency and obtains an extension of time under 37 CFR 1.136(a).

Any inquiry concerning this communication should be directed to Examiner Stephen L. Rawlings, Ph.D., Art Unit 1642, whose telephone number is (703) 305-3008.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

[Signature]
STEPHEN RAWLINGS

Notice to Comply

Application No.

09/806,125

Examiner

Stephen L. Rawlings, Ph.D.

Applicant(s)

MATSUTANI ET AL.

Art Unit

1642

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☒ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☐ 7. Other:

Applicant Must Provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☐ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

PatentIn Software Program Support

Technical Assistance.....703-287-0200

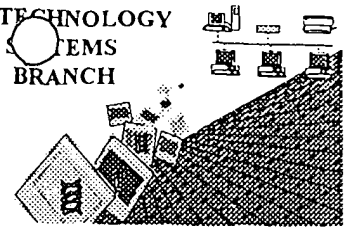
To Purchase PatentIn Software.....703-306-2600

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY

S. Rawlings

Re-run

BIOTECHNOLOGY
SYSTEMS
BRANCH



RAW SEQUENCE LISTING ERROR REPORT

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number: 09/806,125C
Source: 1600
Date Processed by STIC: 5/8/2003

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.

PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:

- 1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,
- 2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY

FOR CRF SUBMISSION AND PATENTIN SOFTWARE QUESTIONS, PLEASE CONTACT MARK SPENCER, 703-308-4212.

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE CHECKER VERSION 4.0 PROGRAM, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE. SEE BELOW FOR ADDRESS:

<http://www.uspto.gov/web/offices/pac/checker>

Applicants submitting genetic sequence information electronically on diskette or CD-Rom should be aware that there is a possibility that the disk/CD-Rom may have been affected by treatment given to all incoming mail.

Please consider using alternate methods of submission for the disk/CD-Rom or replacement disk/CD-Rom.

Any reply including a sequence listing in electronic form should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office, and instead should be sent via the following to the indicated addresses:

1. EFS-Bio (<<http://www.uspto.gov/efb/efs/downloads/documents.htm>> , EFS Submission User Manual - ePAVE)

2. U.S. Postal Service: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

3. Hand Carry directly to:

U.S. Patent and Trademark Office, Technology Center 1600, Reception Area, 7th Floor, Examiner Name, Sequence Information, Crystal Mall One, 1911 South Clark Street, Arlington, VA 22202

Or

U.S. Patent and Trademark Office, Box Sequence, Customer Window, Lobby, Room 1B03, Crystal Plaza Two, 2011 South Clark Place, Arlington, VA 22202

4. Federal Express, United Parcel Service, or other delivery service to: U.S. Patent and Trademark Office, Box Sequence, Room 1B03-Mailroom, Crystal Plaza Two, 2011 South Clark Place, Arlington, VA 22202

Revised 04/24/2003

Does Not Comply
Corrected Diskette Needed

See page 2



1600

RAW SEQUENCE LISTING

DATE: 05/08/2003

PATENT APPLICATION: US/09/806,125C

TIME: 15:01:09

Input Set : A:\EP.txt

Output Set: N:\CRF4\05082003\I806125C.raw

3 <110> APPLICANT: MATSUTANI, Etsuya
 4 NAITO, Kenichiro
 6 <120> TITLE OF INVENTION: Agents For Retarding Change of Hormone-dependent Cancer into
 Hormone-
 7 independent Cancer
 9 <130> FILE REFERENCE: 2556USOP
 11 <140> CURRENT APPLICATION NUMBER: 09/806,125C
 12 <141> CURRENT FILING DATE: 2001-03-28
 14 <150> PRIOR APPLICATION NUMBER: PCT/JP99/05533
 15 <151> PRIOR FILING DATE: 1999-10-07
 17 <150> PRIOR APPLICATION NUMBER: JP 10-286793
 18 <151> PRIOR FILING DATE: 1998-10-08
 20 <160> NUMBER OF SEQ ID NOS: 13
 22 <170> SOFTWARE: PatentIn version 3.0
 24 <210> SEQ ID NO: 1
 25 <211> LENGTH: 10
 26 <212> TYPE: PRT
 27 <213> ORGANISM: Artificial Sequence
 29 <220> FEATURE:
 30 <223> OTHER INFORMATION: synthetic LH-RH peptide derivative
 32 <220> FEATURE:
 33 <221> NAME/KEY: MOD_RES
 34 <222> LOCATION: (6)..(6)
 35 <223> OTHER INFORMATION: D-Leu
 37 <220> FEATURE:
 38 <221> NAME/KEY: MOD_RES
 39 <222> LOCATION: (9)..(9)
 40 <223> OTHER INFORMATION: Pro or Pro-NH-C2H5
 42 <220> FEATURE:
 43 <221> NAME/KEY: MOD_RES
 44 <222> LOCATION: (10)..(10)
 45 <223> OTHER INFORMATION: Gly-NH2 or nothing
 48 <400> SEQUENCE: 1
 W--> 50 Pro His Trp Ser Tyr Xaa Leu Arg Xaa Xaa
 51 1 5 10
 53 <210> SEQ ID NO: 2
 54 <211> LENGTH: 10
 55 <212> TYPE: PRT
 56 <213> ORGANISM: Artificial Sequence
 58 <220> FEATURE:
 59 <223> OTHER INFORMATION: synthetic LH-RH peptide derivative
 61 <220> FEATURE:
 62 <221> NAME/KEY: MOD_RES
 63 <222> LOCATION: (6)..(6)

RAW SEQUENCE LISTING

DATE: 05/08/2003

PATENT APPLICATION: US/09/806,125C

TIME: 15:01:09

Input Set : A:\EP.txt

Output Set: N:\CRF4\05082003\I806125C.raw

```

64 <223> OTHER INFORMATION: DLeu, DAla, DTrp, DSer(tBut), D2Nal, DHis(ImBzl)
66 <220> FEATURE:
67 <221> NAME/KEY: MOD_RES
68 <222> LOCATION: (9)..(9)
69 <223> OTHER INFORMATION: Pro or Pro-NH-C2H5
71 <220> FEATURE:
72 <221> NAME/KEY: MOD_RES
73 <222> LOCATION: (10)..(10)
74 <223> OTHER INFORMATION: Gly-NH2 or nothing
77 <400> SEQUENCE: 2
W--> 79 Pro His Trp Ser Tyr Xaa Leu Arg Xaa Xaa
      80 1          5          10
82 <210> SEQ ID NO: 3
83 <211> LENGTH: 11
84 <212> TYPE: PRT
85 <213> ORGANISM: Artificial Sequence
87 <220> FEATURE:
88 <223> OTHER INFORMATION: synthetic LH-RH peptide derivative
90 <220> FEATURE:
91 <221> NAME/KEY: MOD_RES
92 <222> LOCATION: (1)..(1)
93 <223> OTHER INFORMATION: N(4H2-furoyl)Gly, NAc
96 <220> FEATURE:
97 <221> NAME/KEY: MOD_RES
98 <222> LOCATION: (2)..(2)
99 <223> OTHER INFORMATION: D2Nal
102 <220> FEATURE:
103 <221> NAME/KEY: MOD_RES
104 <222> LOCATION: (3)..(3)
105 <223> OTHER INFORMATION: D4ClPhe
108 <220> FEATURE:
109 <221> NAME/KEY: MOD_RES
110 <222> LOCATION: (4)..(4)
111 <223> OTHER INFORMATION: D3Pal
115 <220> FEATURE:
116 <221> NAME/KEY: MOD_RES
117 <222> LOCATION: (6)..(6)
118 <223> OTHER INFORMATION: NMeTyr, Tyr, Aph(Atz), NMeAph(Atz)
121 <220> FEATURE:
122 <221> NAME/KEY: MOD_RES
123 <222> LOCATION: (7)..(7)
124 <223> OTHER INFORMATION: DLys(Nisp), DCit, DLys(AzaglyNic), DLys(AzaglyFur), DhArg
(Atz), D
125 hc
128 <220> FEATURE:
129 <221> NAME/KEY: MOD_RES
130 <222> LOCATION: (9)..(9)
131 <223> OTHER INFORMATION: Lys(Nisp), Arg, hArg(Et2)
134 <400> SEQUENCE: 3
W--> 136 Xaa Xaa Xaa Xaa Ser Xaa Xaa Leu Xaa Pro Xaa

```

ALL Xaa Location
must be explained in a
Feature.

RAW SEQUENCE LISTING

DATE: 05/08/2003

PATENT APPLICATION: US/09/806,125C

TIME: 15:01:09

Input Set : A:\EP.txt

Output Set: N:\CRF4\05082003\I806125C.raw

```

137 1      5      10
139 <210> SEQ ID NO: 4
140 <211> LENGTH: 6
141 <212> TYPE: PRT
142 <213> ORGANISM: Artificial Sequence
144 <220> FEATURE:
145 <223> OTHER INFORMATION: synthetic kinase consensus target peptide
147 <400> SEQUENCE: 4
149 His Arg Asp Leu Ala Ala
150 1      5
152 <210> SEQ ID NO: 5
153 <211> LENGTH: 5
154 <212> TYPE: PRT
155 <213> ORGANISM: Artificial Sequence
157 <220> FEATURE:
158 <223> OTHER INFORMATION: synthetic kinase consensus target peptide
160 <400> SEQUENCE: 5
162 Ser Asp Val Trp Ser
163 1      5
165 <210> SEQ ID NO: 6
166 <211> LENGTH: 16
167 <212> TYPE: DNA
168 <213> ORGANISM: Artificial Sequence
171 <220> FEATURE:
172 <223> OTHER INFORMATION: primer
174 <220> FEATURE:
175 <221> NAME/KEY: misc_feature
176 <222> LOCATION: (4)..(4)
177 <223> OTHER INFORMATION: C or A
180 <220> FEATURE:
181 <221> NAME/KEY: misc_feature
182 <222> LOCATION: (3)..(3)
183 <223> OTHER INFORMATION: C or T
186 <220> FEATURE:
187 <221> NAME/KEY: misc_feature
188 <222> LOCATION: (9)..(10)
189 <223> OTHER INFORMATION: C or T
192 <400> SEQUENCE: 6
W--> 193 canngggann ggcbgc 16
196 <210> SEQ ID NO: 7
197 <211> LENGTH: 16
198 <212> TYPE: DNA
199 <213> ORGANISM: Artificial Sequence
201 <220> FEATURE:
202 <223> OTHER INFORMATION: primer
204 <220> FEATURE:
205 <221> NAME/KEY: misc_feature
206 <222> LOCATION: (2)..(2)
207 <223> OTHER INFORMATION: a or g

```

RAW SEQUENCE LISTING

DATE: 05/08/2003

PATENT APPLICATION: US/09/806,125C

TIME: 15:01:09

Input Set : A:\EP.txt

Output Set: N:\CRF4\05082003\I806125C.raw

```

210 <220> FEATURE:
211 <221> NAME/KEY: misc_feature
212 <222> LOCATION: (8)..(8)
213 <223> OTHER INFORMATION: c or a
216 <220> FEATURE:
217 <221> NAME/KEY: misc_feature
218 <222> LOCATION: (11)..(11)
219 <223> OTHER INFORMATION: g or a
222 <220> FEATURE:
223 <221> NAME/KEY: misc_feature
224 <222> LOCATION: (14)..(14)
225 <223> OTHER INFORMATION: a or g
228 <400> SEQUENCE: 7
W--> 229 anctccanac ntcnct 16
232 <210> SEQ ID NO: 8
233 <211> LENGTH: 17
234 <212> TYPE: DNA
235 <213> ORGANISM: Artificial Sequence
237 <220> FEATURE:
238 <223> OTHER INFORMATION: primer
240 <220> FEATURE:
241 <221> NAME/KEY: misc_feature
242 <222> LOCATION: (3)..(3)
243 <223> OTHER INFORMATION: c or t
246 <220> FEATURE:
247 <221> NAME/KEY: misc_feature
248 <222> LOCATION: (4)..(4)
249 <223> OTHER INFORMATION: c or a
252 <220> FEATURE:
253 <221> NAME/KEY: misc_feature
254 <222> LOCATION: (6)..(6)
255 <223> OTHER INFORMATION: g or a
258 <220> FEATURE:
259 <221> NAME/KEY: misc_feature
260 <222> LOCATION: (10)..(10)
261 <223> OTHER INFORMATION: c or t
264 <220> FEATURE:
265 <221> NAME/KEY: misc_feature
266 <222> LOCATION: (12)..(12)
267 <223> OTHER INFORMATION: g or t
270 <220> FEATURE:
271 <221> NAME/KEY: misc_feature
272 <222> LOCATION: (15)..(15)
273 <223> OTHER INFORMATION: a or t
276 <400> SEQUENCE: 8
W--> 277 canngngacn tngcngc 17
280 <210> SEQ ID NO: 9
281 <211> LENGTH: 16
282 <212> TYPE: DNA

```


RAW SEQUENCE LISTING

DATE: 05/08/2003

PATENT APPLICATION: US/09/806,125C

TIME: 15:01:09

Input Set : A:\EP.txt

Output Set: N:\CRF4\05082003\I806125C.raw

```

283 <213> ORGANISM: Artificial Sequence
285 <220> FEATURE:
286 <223> OTHER INFORMATION: primer
288 <220> FEATURE:
289 <221> NAME/KEY: misc_feature
290 <222> LOCATION: (2)..(2)
291 <223> OTHER INFORMATION: a or g
294 <220> FEATURE:
295 <221> NAME/KEY: misc_feature
296 <222> LOCATION: (8)..(8)
297 <223> OTHER INFORMATION: a or c
300 <220> FEATURE:
301 <221> NAME/KEY: misc_feature
302 <222> LOCATION: (14)..(14)
303 <223> OTHER INFORMATION: a or c
306 <400> SEQUENCE: 9
W--> 307 anctccanac gtenga 16
310 <210> SEQ ID NO: 10
311 <211> LENGTH: 17
312 <212> TYPE: DNA
313 <213> ORGANISM: Artificial Sequence
315 <220> FEATURE:
316 <223> OTHER INFORMATION: primer
318 <220> FEATURE:
319 <221> NAME/KEY: misc_feature
320 <222> LOCATION: (3)..(3)
321 <223> OTHER INFORMATION: c or t
324 <220> FEATURE:
325 <221> NAME/KEY: misc_feature
326 <222> LOCATION: (4)..(4)
327 <223> OTHER INFORMATION: c or a
330 <220> FEATURE:
331 <221> NAME/KEY: misc_feature
332 <222> LOCATION: (6)..(6)
333 <223> OTHER INFORMATION: g or a
336 <220> FEATURE:
337 <221> NAME/KEY: misc_feature
338 <222> LOCATION: (10)..(10)
339 <223> OTHER INFORMATION: c or t
342 <220> FEATURE:
343 <221> NAME/KEY: misc_feature
344 <222> LOCATION: (15)..(15)
345 <223> OTHER INFORMATION: a or g
348 <400> SEQUENCE: 10
W--> 349 canngngacn tggcngc 17
352 <210> SEQ ID NO: 11
353 <211> LENGTH: 16
354 <212> TYPE: DNA
355 <213> ORGANISM: Artificial Sequence

```

RAW SEQUENCE LISTING ERROR SUMMARY
PATENT APPLICATION: US/09/806,125C

DATE: 05/08/2003
TIME: 15:01:10

Input Set : A:\EP.txt
Output Set: N:\CRF4\05082003\I806125C.raw

Please Note:

Use of n and/or Xaa have been detected in the Sequence Listing. Please review the Sequence Listing to ensure that a corresponding explanation is presented in the <220> to <223> fields of each sequence which presents at least one n or Xaa.

Seq#:1; Xaa Pos. 6,9,10
Seq#:2; Xaa Pos. 6,9,10
Seq#:3; Xaa Pos. 1,2,3,4,6,7,9,11
Seq#:6; N Pos. 3,4,9,10
Seq#:7; N Pos. 2,8,11,14
Seq#:8; N Pos. 3,4,6,10,12,15
Seq#:9; N Pos. 2,8,14
Seq#:10; N Pos. 3,4,6,10,15
Seq#:11; N Pos. 2,8,11,14

VERIFICATION SUMMARY

DATE: 05/08/2003

PATENT APPLICATION: US/09/806,125C

TIME: 15:01:10

Input Set : A:\EP.txt

Output Set: N:\CRF4\05082003\I806125C.raw

L:50 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:1 after pos.:0
L:79 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:2 after pos.:0
L:136 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:3 after pos.:0
L:193 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:6 after pos.:0
L:229 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:7 after pos.:0
L:277 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:8 after pos.:0
L:307 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:9 after pos.:0
L:349 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:10 after pos.:0
L:385 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:11 after pos.:0